ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
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COMMENTS:

DOES NOT CONTAIN CBI

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FUTUREFUEL
CHEMICAL COMPANY
Superior chemistry. Sustainable fuels.

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February 5, 2013

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TSCA Confidential Business Information Center (7407M)
EPA East - Room 6428 Attn: Section 8(e)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Re: TSCA Section 8(e) Notification: 1,3-Benzenedicarboxylic acid,5-sulfo-,monosodium salt testing program (CAS no. 6362-79-4).

Dear TSCA Section 8(e) Coordinator:

In accordance with the provisions of Section 8(e) of the Toxic Substances Control Act (TSCA), as interpreted in the TSCA Section 8(e) Policy Statement and Guidance, Fed. Reg. 33129 (June 3, 2003) and other Agency guidance, FutureFuel Chemical Company submits the following information concerning an *in vivo* combined repeated dose toxicity and reproductive and developmental toxicity screening study on the test substance 1,3-Benzenedicarboxylic acid,5-sulfo-,monosodium salt (CAS no. 6362-79-4). This study was conducted for the purposes of REACH registration in Europe.

Study Design

An OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test) was conducted in rats with the test substance 1,3-Benzenedicarboxylic acid,5-sulfo-,monosodium salt (CAS no. 6362-79-4). The test substance was administered by daily oral gavage to male and female Wistar Han rats at dose levels of 0 (control), 100, 300 and 1000 mg/kg/day. Males were exposed for 2 weeks prior to mating, during mating, and up to termination (for 29 days). The females were exposed for 2 weeks prior to mating, during mating, during post-coitum, and at least 4 days of lactation (for 43-53 days). Pups were sacrificed after Day 4 of lactation.

The following observations and examinations were evaluated: mortality / viability, clinical signs (daily), functional observations and locomotor activity (end of treatment), body weight and food consumption (at least at weekly intervals), clinical pathology (end of treatment), macroscopy at termination, organ weights and histopathology on a selection of tissues, and reproduction / developmental parameters, consisting of mating, fertility and conception indices, precoital time,

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number of corpora lutea and implantation sites, gestation index and duration, parturition, maternal care, sex ratio and early postnatal pup development (mortality, clinical signs, body weights and macroscopy).

Study Results

Other than minor squamous hyperplasia of the limiting ridge of the forestomach, treatment with the test substance by oral gavage in male and female Wistar Han rats at dose levels of 100, 300 and 1000 mg/kg body weight/day produced no other significant or relevant toxicological effects.

The test substance induced a statistically significant increase in the sex ratio (male/female) in pups at the highest dose of 1000 mg/kg body weight/day with more female than male pups produced (62% female pups compared to 47% of the control group). No similar effects or any other statistically significant developmental effects were note in any other dose groups in this study. Although historical control data from this testing laboratory indicated two studies in which comparable percentages of female pups were noted, a possible relationship to treatment could not be excluded for the changed sex ratio in the current study.

Based on the results of this testing, the test material may possibly produce developmental effects when administered at high dose levels.

Risk of Human Exposure

The test material is used solely as a chemical intermediate and thus consumer exposures to the substance are not relevant. The material is a non-volatile organic salt with little potential to aerosolize during manufacturing or processing. During manufacture, appropriate industrial hygiene procedures are in place to minimize worker exposures. Also, manufacturing procedures employed greatly reduce or eliminate any potential environmental exposures.

If you have any questions, please contact me.

Sincerely yours,

Jerry Patterson

Jerry Patterson
Product Safety Manager

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Dear TSCA Section 8(e) Coordinator:

In accordance with the provisions of Section 8(e) of the Toxic Substances Control Act (TSCA), as interpreted in the TSCA Section 8(e) Policy Statement and Guidance, Fed. Reg. 33129 (June 3, 2003) and other Agency guidance, FutureFuel Chemical Company submits the following information concerning an in vitro cytogenetics study on the test substance 1,3-Benzenedicarboxylic acid, 5-sulfo-, monosodium salt (CAS no. 6362-79-4). This study was conducted for the purposes of REACH registration in Europe. A final signed report was received from the testing laboratory and per our letter dated November 2012; we are providing a summary of that final report:

Study Design

An OECD Guideline 487: In vitro mammalian cell micronucleus test (adapted 22 July 2010) was conducted with the test substance 1,3-Benzenedicarboxylic acid,5-sulfo-, monosodium salt.

In the first cytogenetic assay, 1,3-Benzenedicarboxylic acid,5-sulfo-,monosodium salt was tested up to 2400 and 2682 (0.01 M) µg/ml for a 3 hours exposure time with a 27 hours harvest time in the absence and presence of S9-fraction, respectively. Appropriate toxicity was reached at this dose level. The positive control chemicals, mitomycin C and cyclophosphamide both produced a statistically significant increase in the number of binucleated cells with micronuclei. The positive control chemical colchicine produced a statistically significant increase in the number of mononucleated cells with micronuclei. The number of mono- and binucleated cells with micronuclei found in the solvent control cultures in the presence of S9-mix was within the laboratory historical control data range. Although the number of binucleated cells with micronuclei found in the solvent control cultures in the absence of S9-mix was above the laboratory historical control data range the outcome of the study was clearly positive. It was

therefore concluded that the test conditions were adequate and that the metabolic activation system (S9-mix) functioned properly. At the 3 hours exposure time both in the absence and presence of S9-mix, 1,3-Benzenedicarboxylic acid,5-sulfo-,monosodium salt induced a statistically significant increase in the number of binucleated cells with micronuclei at the highest concentration tested. In addition, in the presence of S9-mix, in one of the duplicate cultures, the number of mononucleated cells with micronuclei was also statistically significant increased. These results indicate that 1,3-Benzenedicarboxylic acid,5-sulfo-,monosodium salt is positive in the *in vitro* micronucleus study and might be considered an aneugenic or clastogenic compound.

Risk of Human Exposure

The test material is used solely as a chemical intermediate and thus consumer exposures to the substance are not relevant. The material is a non-volatile organic salt with little potential to aerosolize during manufacturing or processing. During manufacture, appropriate industrial hygiene procedures are in place to minimize worker exposures. Also, manufacturing procedures employed greatly reduce or eliminate any potential environmental exposures.

If you have any questions, please contact me.

Sincerely yours,

Jerry Patterson
Product Safety Manager

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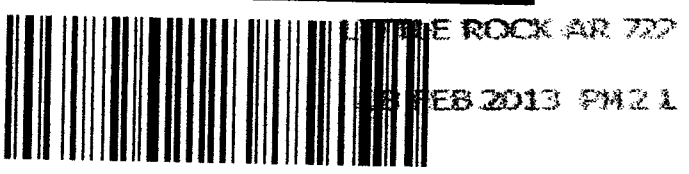

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